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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,741	03/31/2004	Alexander A. Krakovsky		5136
7590	03/23/2006			
John R. Ross P.O. Box 2138 Del Mar, CA 92014			EXAMINER ROBERTS, DARIN	
			ART UNIT 3762	PAPER NUMBER
DATE MAILED: 03/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/813,741	KRAKOVSKY, ALEXANDER A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Darin R. Roberts	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The examiner has noticed that no Information disclosure statement (IDS) was filed with the application filed on 11/05/2006. Please consider Including an IDS with your next correspondence.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 1-7 & 9-11 are rejected** under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 1, 4, 5, & 9-11 are directed toward the claiming of structures being in contact with or implanted within the body, such claiming amounts to an inferential recitation of the body, which renders these claims non-statutory.

#### ***Claim Objections***

**Claims 2, 4, 5, & 7 are objected to** under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

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In reference to claims 2, 4, & 5, these claims do not and any further structure to the device thus failing to further limit the claim upon which they are dependent.

In reference to claim 7, claim 7 is redundant of Claim 6 because the location in which the stimulation is provided does not further limit the structure of the claimed device.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

**Claims 1, 2, 4, 5, & 8 are rejected** under 35 U.S.C. 102(a) as being anticipated by Gerber (US 20050113878 A1).

In reference to **claims 1, 2 & 8**, the Gerber publication teaches the use of an implantable stimulator (see abstract) inherently capable of being inserted beneath the skin of the user, due to the fact that it is implantable, the Gerber device is also capable of providing sexual stimulation (see abstract). The Gerber device comprises of a control device that is capable of providing pulses, such a device can be referred to as pulse generator (see pp. 0062). The Gerber publication also teaches a device that possesses an external control mechanism (see pp. [0073]), such a device is capable of being controlled by a lover or the

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actual patient. The Gerber device also possesses a programmable processor to produce the desired pulse shapes (see pp. [0062]). The Gerber device possesses electrodes fully capable of being inserted into the epidural space of the individual's sacrum (see fig. 3, pp. [0097], & pp. [0116]), Gerber teaches the use of leads, which can be described as electrical conductors. Such conductors are capable of connecting to a pulse generator (see pp. [0081]).

In reference to **claims 4 & 5**, because both males and females possess a spinal chord the Gerber device is inherently capable of providing spinal chord stimulation to both men and women.

In reference to **claim 11**, though it is not explicitly stated, the use of such a device on human beings is implied in the Gerber publication (see fig 1).

**Claims 1, 6, 7, 8 & 11 are rejected** under 35 U.S.C. 102(e) as being anticipated by Whitehurst et al. (US 6862479 B1).

In reference to claim 1, the Whitehurst patent teaches the use of a stimulator that provides stimulation to a user's sexual organs (see abstract) comprising of a stimulator inherently capable of being installed under the skin due to the fact that it is implantable (see abstract). The Whitehurst stimulator possesses a pulse generator (see column 4, lead line 12) as well as a receiver for receiving instructions capable of being sent by the user or the user's lover (see column 4, lead lines 58-62), a programmable processor controlling a pulse generator for sending the desired pulse shapes (see column 10, lines 62-67) and electrodes capable of being inserted into the epithelial space via the sacrum (see

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column 5, lines 57-61 & Fig. 1, & fig. 2B). Whitehurst also teaches the use of an electrical conductor referred to as a lead connecting the pulse generator to an electrode (see column 8, lead lines 59-64).

In reference to **claims 6 & 7**, the Whitehurst device teaches providing electrical stimulation to the spinal chord of the user, as well as administering drugs to a patient's spinal chord to stimulate said spinal chord. The Whitehurst et al. patent inherently possesses a reservoir for administering drugs to a patient's spinal chord if it is capable of drug delivery.

In reference too **claims 8 & 11**, Whitehurst teaches correcting impotency in a male animal comprising the steps of surgically implanting a device under the skin of said animal (see abstract) and possessing a programmable electronic stimulator comprising an electrical pulse generator (see column 5, lines 7-14), and strategically implanting an electrode in a epidural region of said animal's sacrum (see column 4, lead lines 6-16). Whitehurst et al. also teaches providing an electrical connection between said pulse generator and said electrode (see column 4, lead lines 5-9) and providing an electronic control for controlling said stimulator for so as to produce erection in said male animal (see column 6, lines 49-59 & column 4, lead lines 30-37). Though the Whitehurst patent does not explicitly state that the animal to be stimulated is a human, the stimulation of such an animal is implied (see fig. 1)

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claim 3 is rejected** under 35 U.S.C. 103(a) as being unpatentable over Gerber (US 20050113878 A1).

In reference to **claim 3**, according to MPEP 2144.04 (B) the duplication of parts "has no patentable significance unless a new and unexpected result is produced". The Gerber publication teaches the use of one pulse generator as well as one lead (see pp. [0081]), but Gerber does not teach the use of multiple pulse generators in conjunction with multiple leads. However it would have been obvious to one of ordinary skill in the art to employ the use of multiple pulse

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generators and leads to allow for the stimulation of multiple sites at the same time.

**Claims 9 & 10 are rejected** under 35 U.S.C. 103(a) as being unpatentable over Whitehurst et al. (US 6862479 B1).

In reference to ***claims 9 & 10***, the Whitehurst et al. device does not teach the spinal chord stimulation of domesticated or wild animals, however Whitehurst et al. does teach the stimulation of the human spinal chord and all vertebrates do possess a spinal chord.

Thus it would have been obvious to one of ordinary skill in the art to alter the Whitehurst et al. device to fit other vertebrates (such as wild and domesticated animals) for the purposes of testing.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571) 272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-9900.




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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Darin Roberts  
Patent Examiner  
Art Unit 3762

D. R.

  
JEFFREY R. JASTRZAB  
PRIMARY EXAMINER  
3/20/06